

BEST AVAILABLE COPY

REMARKS

I. Overview

Claims 1-3 and 5-10 are currently pending in this application. Claim 4 has been canceled. Claims 1, 5, 7 and 9 have been amended. Support for these amendments can be found in the Published Specification at paragraphs 42, 45, 46, and 52. The present response is an earnest effort to place all claims in proper form for immediate allowance. Reconsideration and passage to issuance is therefore respectfully requested.

II. Claim Rejection Under 35 U.S.C. § 102(b) Over Franz 5,527,831

Claims 5-6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Franz, Patent No. 5,527,831. The Examiner writes the claims remain anticipated by Franz because Franz discloses administration of an identical agent, i.e., xylitol, to a patient, using Applicant's claimed method steps. Accordingly the resulting effect of a reduction in the ionic strength of surface fluid leading to antimicrobial activity against infectious cells is an inherent characteristic of the method.

To anticipate, the prior art must contain each and every limitation in the claim. As amended, claim 5 recites: "administering to an external eye a composition comprising an antibiotic and an effective amount of a non-ionic osmolyte". At paragraph 46 in the Published Specification, Applicants teach that "xylitol (or other low permeability, non-ionic osmolyte might be used in the formulation of antibiotics ... delivered as solutions to the external eye.... In such applications, xylitol could yield additive or synergistic effects of the activity of pharmaceutical antibiotics with the endogenous antimicrobials."

BEST AVAILABLE COPY

In contrast, '831 teaches the use of a solution containing "a polyhydroxyalcohol which is effective for lowering intraocular pressure of aqueous humor" as well as the use of this solution in conjunction with other drugs ...for the topical treatment of increased intraocular pressure of aqueous humor." '831, Col. 4, lines 48-58. Thus, '831 does not teach or suggest each element of independent claim 5 or dependent claim 6 because '831 teaches applying a solution of polyhydroxyalcohol and optionally drugs for decreasing intraocular pressure, rather than a composition comprising an antibiotic and an effective amount of a non-ionic osmolyte for treatment of bacterial infections. Therefore, Applicants request that the rejection to claims 5-6 under 35 U.S.C. §102(b) be withdrawn and reconsidered.

III. Claim Rejection Under 35 U.S.C. § 102(e) Over Jones 6,054,143

Claims 1-4 and 7-8 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Jones, Patent No. 6,054,143. The Examiner writes that the instant invention recites treatment and prevention of infectious microbial cells, such as respiratory infections, by enhancing the main antibacterial defense system through administration via aerosol or powder. The Examiner submits that the killing of the bacteria is inherent in the disclosed method. Furthermore, the Examiner writes that by killing the bacteria is the method able to reduce the respiratory infections and that Jones teaches administration of an identical agent, i.e., xylitol to a host using Applicant's claimed method steps. The Examiner writes that accordingly the resulting reduction in the ionic strength of the surface fluid leading to antimicrobial activity against infectious cells in an inherent characteristic of the method.

To anticipate, the prior art must contain each and every limitation in the claim. As amended, claim 1 recites: "administering to a lower respiratory tract epithelium surface an

BEST AVAILABLE COPY

effective amount of a non-ionic osmolyte". At paragraphs 42, 45 and 52 in the Published Specification, Applicants teach applying xylitol to the apical surface of human airway epithelia, including tracheal and bronchial epithelia.

In contrast, Jones teaches the use of a spray containing xylitol for "cleaning of the nasopharynx, reduction of the bacteria count in the nasopharynx and a reduction in infections associated with those bacteria." '143, Col. 2, lines 31-34. Thus, Jones does not teach or suggest each element of claim 1 or dependent claims 2-4 because Jones teaches applying xylitol to nasopharynx for treating upper respiratory infections, not applying xylitol to a lower respiratory tract epithelium surface to decrease airway surface liquid salt concentration as a possible treatment for cystic fibrosis.

With regard to claims 7 and 8, the '143 patent must contain each and every limitation in the claim to anticipate. As amended, claim 7 recites: "administering to the oral pharynx a composition comprising an antibiotic and an effective amount of a non-ionic osmolyte, wherein said composition is not used to kill strep pneumonia". At paragraph 46 in the Published Specification, Applicants teach that "xylitol (or other low permeability, non-ionic osmolyte) might be used in the formulation of antibiotics ... delivered as solutions to the ...pharynx. In such applications, xylitol could yield additive or synergistic effects of the activity of pharmaceutical antibiotics with the endogenous antimicrobials."

In contrast, Jones teaches "the use of xylitol/xylose .. in combination with a first line antibiotic for treatment of most upper respiratory conditions where strep pneumonia is the agent involved with the infection." '143, Col. 3, lines 60-63. Thus, Jones does not teach or suggest each element of claim 7 or dependent claim 8 because Jones only teaches applying xylitol with a first line antibiotic to treat strep pneumonia, not applying a composition comprising any

BEST AVAILABLE COPY

antibiotic and an effective amount of a non-ionic osmolyte to kill bacteria other than strep pneumonia.

Therefore since Jones does not teach all the elements of independent claims 1 and 7, Applicants request that the rejection to claims 1-3 and 7-8 under 35 U.S.C. §102(e) be withdrawn and reconsidered.

IV. Claim Rejection Under 35 U.S.C. § 102(a) Over WO 99/27922 ('922)

Claims 9-10 stand rejected under 35 U.S.C. § 102(a) as being anticipated by the PCT Published Patent Application No. WO 99/27922. The Examiner writes that WO '922 discloses a method of treating vaginal yeast infections by administering xylitol to a patient in need thereof. The Examiner writes that the method of WO '922 serves to kill the yeast (i.e., infectious cells) causing the infection. The Examiner writes that WO '922 continues to anticipate the claims because WO '922 disclose administration of an identical agent, i.e., xylitol to the vagina of a patient using Applicant's claimed method steps. The Examiner writes that accordingly the resulting reduction in the ionic strength of surface fluid leading to antimicrobial activity against infectious cells is an inherent characteristic of the method. Therefore, the Examiner writes it is reasonable to conclude that the same patient is being administered the same composition by the same mode of administration in the same amount in both the instant claims and the WO '922 reference.

To anticipate, the prior art must contain each and every limitation in the claim. As amended, claim 9 recites: "administering to a vaginal surface a composition comprising an antibiotic and an effective amount of a non-ionic osmolyte". At paragraph 46 in the Published Specification, Applicants teach that "xylitol might be used in the formulation of antibiotics ...

BEST AVAILABLE COPY

delivered as solutions to ... the vagina.... In such applications, xylitol could yield additive or synergistic effects of the activity of pharmaceutical antibiotics with the endogenous antimicrobials."

In contrast, WO '922 teaches the use of a composition containing xylitol for "the treatment or prophylaxis of mucosal yeast infection in mammals", as well as the simultaneous administration of antifungal drugs. WO '922, at page 4, fourth paragraph. Thus, WO '922 does not teach or suggest each element of independent claim 9 or dependent claim 10 because WO '922 teaches applying a composition including xylitol and optionally antifungals for the treatment of oral or vaginal yeast infections, rather than a composition comprising an antibiotic and an effective amount of a non-ionic osmolyte for treatment of bacterial infections. Therefore, Applicants request that the rejection to claims 9-10 under 35 U.S.C. §102(a) be withdrawn and reconsidered.

V. Conclusion

Please consider this a three-month extension of time from September 16, 2005 to December 16, 2005 and charge Deposit Account No. 26-0084 the amount of \$510.00 for this extension. No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

BEST AVAILABLE COPY

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



EDMUND J. SEASE, Reg. No. 24,741
McKEE, VOORHEES & SEASE, P.L.C.
801 Grand Avenue, Suite 3200
Des Moines, Iowa 50309-2721
Phone No: (515) 288-3667
Fax No: (515) 288-1338
CUSTOMER NO: 22885

Attorneys of Record

- bja -